

Appln No. 09/711,648
Amdt date October 28, 2010
Reply to Office action of May 28, 2010

REMARKS/ARGUMENTS

In the Final rejection dated May 28, 2010, the Examiner maintained the rejection of claims 1-3, 5-20, 23-25, 27, 28, 30-35 and 44-50 under 35 U.S.C. §103(a) as allegedly obvious over Abele (U.S. Patent No. 5,403,311) in view of West, et al. (U.S. Patent No. 5,318,525) and Langer, et al. (U.S. Patent no. 6,004,295). In maintaining this rejection, the Examiner argues that Abele discloses "a rounded end portion 52...coated with a conductive metal, such as gold to provide a first electrode" and "[a] projectable, tissue-penetrable needle tip electrode 56, representing a second electrode isolated from the gold coated first electrode." Office action, page 6 (citing column 8, line 60 of Abele). In making these arguments, the Examiner appears to argue that the rounded end portion 52 coated with a metal is akin to the recited penetration monitoring electrode. Applicant respectfully traverses.

As noted in the passage relied on by the Examiner, the rounded end portion 52 is "secured to the end of a catheter shaft 54." Column 8, lines 59-60. Additionally, that passage describes the tissue-penetrable needle tip as projectable (as shown in Figure 6) and retractable (as shown in Figure 7). As can be seen from Figure 7, the needle tip 56 is retractable into the rounded end portion 52 which the Examiner asserts is akin to the recited penetration monitoring electrode. As the needle tip is retractable into and projectable from the rounded end portion 52, the rounded end portion cannot be akin to the recited penetration monitoring electrode. In particular, independent claims 1, 9 and 23 each recite a penetration monitoring electrode *fixedly* mounted *on* the injection needle. As the needle tip in Abele is projectable and retractable with respect to the rounded end portion 52, it cannot be *fixedly* mounted *on* the injection needle. Indeed, the Examiner appears to admit that Abele fails to teach a penetration monitoring electrode fixedly mounted on the injection needle. Office action, page 3 (stating "Abele does not teach a puller wire and deflection control handle for controlling the deflection of the tip section *or the penetration monitoring electrode fixedly mounted on the needle tip*"). Accordingly, independent claims 1, 9 and 23, and all claims dependent therefrom, including claims 2, 3, 5-8, 10-20, 24, 25, 27, 28, 30-35 and 44-50, are allowable over Abele, West and Langer.

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In addition, in her response to Applicant's previous arguments, the Examiner stated that "[i]t [is] unclear why applicant was reviewing the teachings of Langer regarding [an isolated electrode]." Final rejection, page 6. In response, Applicant notes that earlier in the Office action, the Examiner admitted that Abele fails to teach a penetration monitoring electrode mounted on the injection needle. Final rejection, page 3. The Examiner also earlier relied on Langer to remedy that deficiency, arguing that element 80 depicted in Figures 8A and 8B is akin to the recited penetration monitoring electrode. However, as discussed in Applicant's previous response, Langer fails to teach or suggest that the recording electrode 80 is electrically insulated from the injection needle. To the extent the Examiner is arguing that it would have been obvious to combine the teachings of Abele and Langer to arrive at the recited penetration monitoring electrode fixedly mounted on the injection needle and electrically insulated from the injection needle, Applicant respectfully traverses.

As discussed above, Abele discloses a rounded end portion electrode 52 and a needle tip that is projectable and retractable with respect to that electrode. As such, those of ordinary skill in the art would have found no reason to replace that rounded end portion electrode with an electrode *fixedly* mounted to the needle (such as the one disclosed in Langer) since such a configuration would destroy the ability of the needle tip to project and retract with respect to the electrode. Moreover, as Abele nowhere teaches or suggests an electrode *fixedly mounted* on the needle, Abele also nowhere teaches or suggests that such an electrode should be electrically insulated from the needle. As Langer also fails to teach or suggest an electrode that is electrically insulated from the needle, the combination of Abele and Langer also fails to teach or suggest a penetration monitoring electrode fixedly mounted on the injection needle *and* electrically insulated from the injection needle, as recited in independent claims 1, 9 and 23.

Also, in rejecting original claims 13, 15, 45 and 47, the Examiner simply states that Abele discloses "all of the claimed methods." Office action, page 5. However, Abele nowhere teaches or suggests a method in which a determining step comprises measuring the *impedance* across the electrode mounted on the injection needle, as recited in claim 45, or a method in which a determining step comprises *comparing the impedance* across the electrode mounted on

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the injection needle to the impedance across the additional electrode, as recited in claim 45. Indeed, Abele nowhere teaches or suggests the electrode mounted on the injection needle, as admitted by the Examiner. Final rejection, page 3 (stating that Abele does not teach the penetration monitoring electrode fixedly mounted on the needle tip). Also, Abele nowhere teaches or suggests a method in which a determining step comprises measuring the *impedance* across the distal end of the injection needle, as recited in claim 13, or a method in which a determining step comprises *comparing the impedance* across the distal end of the injection needle to the impedance across the additional electrode. As Abele nowhere teaches or suggests these features, and none of West, Langer and Cosman remedy this deficiency, claims 13, 15, 45 and 47 are independently allowable over these references.

The Examiner also rejected claims 4 and 26 under 35 U.S.C. §103(a) as allegedly obvious over Abele, West and Langer in view of Cosman (U.S. Patent No. 4,966,597). However, each of claims 4 and 26 depends from one of independent claims 1, 9 and 23, all of which are allowable over Abele, West and Langer as discussed above. Cosman fails to remedy the deficiencies of Abele, West and Langer, as Cosman, either alone or in combination with Abele, West and Langer fails to teach or suggest the recited penetration monitoring electrode. Accordingly, independent claims 1, 9 and 23, and claims 4 and 26 which depend therefrom, are allowable over Abele, West, Langer and Cosman.

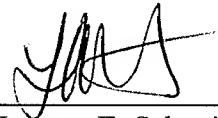
Claims 1-20, 23-28, 30-35 and 44-50 are pending in this application. In light of the above amendments and remarks, Applicant submits that all of pending claims 1-20, 23-28, 30-35 and 44-50 are in condition for allowance. Applicant therefore respectfully requests reconsideration and a timely indication of allowance. However, if there are any remaining issues

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that can be addressed by telephone, Applicant invites the Examiner to contact Applicant's counsel at the number indicated below.

Respectfully submitted,
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